

1. Introduction

This Standard Operating Procedure (SOP) describes the process required to open or reopen research activity during a World Health Organisation (WHO) categorised pandemic at University Hospitals of Leicester NHS Trust.

Many research studies will have closed or set up delayed due to a pandemic having been called. This is due to the fact that many staff will be redeployed to assist on the pandemic clinical front line, but also because many clinical services will be suspended to help to manage the Public Health Crisis.

When the initial pandemic cases have peaked, some clinical services will begin to be brought back on line. In the same way, it may be possible for some research to be re-opened with appropriate changes to the method of delivery or patient visits.

This SOP clarifies the questions to be considered before re-opening research activity and should be read alongside the National Institute of Health Research (NIHR) 'A framework for restarting research studies funded or supported by NIHR which have been paused due to COVID-19' – <https://www.nihr.ac.uk/documents/restart-framework/24886?pr=>

2. Scope

This SOP applies to all staff and external individuals involved in research activity during a WHO categorised pandemic that is **HOSTED** by UHL or where UHL is a research **SITE**.

3. Categorisation of Research

Prior to and during the initial / developing stages of the pandemic; all research activity at UHL will be categorised in accordance with the SOP C-2026 UHL Pandemic Categorisation for research hosted by UHL during a pandemic. The categories are as follows:

1.	Urgent research contributing evidence to the understanding of the pandemic and listed on an Urgent Public Health Research portal. The category 1 studies were further divided to reflect the UHL priority: 1A – UHL First Priority and 1B - all other UHL studies.
2.	Clinical studies where the study protocol contributes to essential clinical care, or where patients would not otherwise receive an essential treatment.
3.	Research studies where protocol driven changes in immunosuppression or other interventions may potentially render patients at a higher risk of infection.
4.	Other
5.	Research contributing evidence to the understanding of the pandemic but not listed on the Urgent Public Health Research portal.

Research that is categorised within numbers '3' and '4' may have cease activity. This SOP is targeted mainly at these studies.

4. Questions to Ask

There are a number of important questions to ask before re-opening research. The first of these should be addressing the viability of the research in a post pandemic age. Each clinical service or area may have different needs and it is expected that all relevant individuals will be engaged during the conversation.

Appendix 1 provides an outline of considerations and questions that should be asked before any individual research study is re-opened. Appendix 2 provides a guidance flow chart for a clinical research service to follow prior to submitting to R&I for approval. It is expected that the Principal Investigator along with wider study management will engage in conversation across the speciality and consider these points as a minimum.

5. Re-Opening / Opening Research

In order to re-open or open research, confirmation that the points in Section 4 have been considered should be sent to R&I along with confirmation from the Sponsor that there is agreement in place for the activity to commence.

Any alterations to patient pathways have been noted and appropriate Non-Substantial or Substantial amendments have been or are planned to be submitted as relevant to the regulatory agencies.

Attention to patient and research safety must be considered. Creative options to continue involvement may be required. Each study may need different solutions but all options should be explored.

Please note that R&I will coordinate Support Department notifications.

6. Responsibilities

Responsibility	Undertaken by	Activity
1 Principal Investigator / Study Team	PI/Study Team	Confirm all aspects considered and alterations in place to commence re-open or opening of studies
2 R&I Office	R&I Office	Update EDGE; provide email confirmation of re-opening study.

7. Legal Liability Statement

Guidelines or Procedures issued and approved by the Trust are considered to represent best practice. Staff may only exceptionally depart from any relevant Trust guidelines or procedures and always only providing that such departure is confined to the specific needs of individual circumstances. In healthcare delivery such departure shall only be undertaken where, in the judgement of the responsible healthcare professional it is fully appropriate and justifiable – such a decision to be fully recorded in the patient's notes and in the research site file.

8. Supporting Documents and Key References

SOP C-2026 UHL Pandemic Categorisation for research hosted by the UHL

SOP C-2027 Appendix 1, 2

9. Key Words

Research, Innovation, Prioritised, Expedited, Pandemic, Covid, Reopen, Feasibility, C&C, Categorisation, Urgent Public Health, UPH

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